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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/222,460	12/29/1998	MARC R. HAMMERMAN	A-64236-3-RF	3124
7590 10/20/2004			EXAMINER	
FLEHR HOHBACH TEST ALBRITTON & HERBERT			GUPTA, ANISH	
SUITE 3400			ART UNIT	
FOUR EMBARCADERO CENTER			PAPER NUMBER	
SAN FRANCISCO, CA 941114187			1654	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/222,460

**Applicant(s)**

HAMMERMAN ET AL.

**Examiner**

Anish Gupta

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-5-04 has been entered.

2. All rejections made in the previous office action are hereby withdrawn and new grounds of rejections follow below.

The terminal disclaimer filed on 8-29-03 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 5,976,524 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the

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contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims <sup>1,4-5,</sup> ~~1-5,~~ 7-9, 22, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrahamson et al. in view of Liu et al.

The claims are drawn to a method for the treatment of metanephric tissue for transplantation into a recipient contacting the tissue, in vitro or at the time of ureteroureterostomy, with a growth factor containing composition.

The reference of Abrahamson et al. teaches implanting metanephroi from E17 rat embryos beneath the renal capsule of five adult rat hosts (see abstract). The reference discloses that continued nephrogenesis occurred after implantation of kidney. The Kidney grafts become rapidly vascularized and there was no evidence of ischemic necrosis over the 9 and 28-day time frame examined (see page 635). The difference between the prior art and the instant application is that the Abrahamson et al. does not teach the administration of a growth factor.

However, Liu et al. teaches that mouse metanephroi were exposed to IGF-I (100ng/mL) in an organ culture for seven days. An enlargement of the metanephroi was observed. The reference concludes that IGF-I has a trophic effect on the embryonic kidney during the postinductive period of metanephric development (see abstract). On page 389 of the reference states that IGF 1 "accelerates and maintains the conversion of induced mesenchyme into the renal epithelium with consequential increase in the size as well as nephron population." Thus, the reference specifically teaches the actions of exogenous IGF-I on metanephric tissue. Therefore, it would have been obvious to expose the metanephric tissue to IGF-I prior to transplantation because because Liu et

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al. teaches the role of IGF-1 in tissue enlargement. Thus, one would be motivated to use exogenous IGF-I on metanephric tissue. As for the time, one could have optimized favorable times of administration via routine experimentation. As a further note, preincubation of the tissue with the growth factor would be similar to the in-vitro methodology disclosed.

4. Claims 1-5, 7-9, 22 and 25 rejected under 35 U.S.C. 103(a) as being unpatentable over Abrahamson et al. in view of Rogers et al.

The claims are drawn to a method for the treatment of metanephric tissue for transplantation into a recipient contacting the tissue, in vitro or at the time of ureteroureterostomy, with a growth factor containing composition.

The reference of Abrahamson et al. teaches implanting metanephroi from E17 rat embryos beneath the renal capsule of five adult rat hosts (see abstract). The reference discloses that continued nephrogenesis occurred after implantation of kidney. The Kidney grafts become rapidly vascularized and there was no evidence of ischemic necrosis over the 9 and 28-day time frame examined (see page 635). The difference between the prior art and the instant application is that the Abrahamson et al. does not teach the administration of a growth factor.

However, Rogers et al. The reference teaches that TGF- $\alpha$ , when administered to the removed metanephroi, was effective in increasing the size of morphological complex of metanephroi. The reference concludes that the peptide is necessary for growth and development of metanephroi in vitro (see abstract). Rogers acknowledges that their methodology is the endogenous blocking of TGF- $\alpha$ . The reference also states that the exogenous EGF induced enhanced differentiation of thick ascending limb-early distal tubules and collection ducts (see page F538). Further, the reference also states that the EGF and TGF- $\alpha$  interact with a common receptor. The reference concludes that

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although the disclosed method difference from exogenous administration of EGF, the effects of TGF- $\alpha$  are consistent with the action of exogenous EGF. Therefore, it would have been obvious that TGF- $\alpha$  would be as effective in differentiation of thick ascending limb-early distal tubules and collection ducts as EGF was when added exogenously. Therefore, one would have been motivated to add exogenous TGF- $\alpha$  or at the least EGF. As for the time, one could have optimized favorable times of administration via routine experimentation. As a further note, preincubation of the tissue with the growth factor would be similar to the in-vitro methodology disclosed.

5. Claims 17, 20, 23, 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. These claims are allowable over the prior art because the art neither teaches nor suggest the administration of VEGF and Vitamin A to metanephric tissue at the time of or after being transplanted into the recipient.

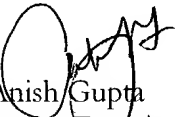
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Anish Gupta  
Patent Examiner

10/15/04